

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IT 02/00680

Re Item I**Basis of the report**

- 1 The amendments filed with the letter dated 26/05/2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:
"with a flat end" do not appear to be disclosed as such in the originally filed application. The drawings cannot be considered to be a sound base for such an amendment because they just give a schematic view of an embodiment of the nebulizer.
- 1.1 Therefore this amendment is not considered for the substantive examination. Therefore, for conformity to the wording of claim 3, the terms "with a flat end" in claim 3 have also not been considered for the substantive examination.

Re Item V**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 2 Reference is made to the following document:
D1: EP-A-0 620 021 (GLENN JOSEPH G ;A & H PRODUCTS INC (US)) 19 October 1994 (1994-10-19) cited in the application
- 3 The closest prior art as regard claim 1 is D1.
- 3.1 The subject matter of this claim differs from this document in that it specifies that "the coating of the body has portions defining extensions of lateral walls of the secondary channel".
In view of this difference, the subject matter of claim 1 is new and therefore meets the requirements of Article 33(2) PCT.
- 3.2 The feature mentioned at the previous point (the extensions of the lateral walls) serves to "consent a better selection of the particles and to consent the coating body to be maintained in a correct operating position compressed between the secondary channel and the base of the tank in such a way that the coating body can not move and rest firmly engaged between the secondary channel and the

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tank". No hint of this feature "extensions of the lateral walls" for the same purpose can be found in the available prior art.

Therefore the subject matter of claim 1 meets the requirements of Article 33(3) PCT.

- 3.3 The device of claim 1 is industrially applicable, and therefore the requirements of Article 33(4) PCT are met.
- 3.4 Claims 2 - 7 are dependent on claim 1 and refer to particular embodiments of their subject matter. In view of that, claims 2 - 7 meet the requirements of Article 33(2) to (4) PCT.

<EP-A-0620021 discloses a nebuliser ampoule for aerosol therapy as in the preamble of Claim 1.>

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piece with the distributor have some important drawbacks.

First of all, because of the presence of the supports of the platelet, it is impossible to assure a flow of air that is substantially symmetrical relative to the axis of the primary conduit. Consequently, the nebulisation that is formed inside the ampoule is not homogeneous.

In the second place, the presence of the supports forces to construct a single pair of channels for aspirating the medical product. Given the geometry of the distributor and of the activator element, the supports inevitably interfere with at least a pair of channels positioned in correspondence with a diameter of the cone, compromising a correct distribution of the medical liquid inside the flow of air present in the ampoule.

<> DISCLOSURE OF THE INVENTION.

The aim of the present invention is to eliminate the aforesaid drawbacks making available a nebuliser ampoule provided with an activator element able to assure a primary flow of air, substantially symmetrical relative to the axis of the primary conduit.

Another aim of the present invention is to propose a nebuliser ampoule provided with a distributor element which allows to obtain any number of channels, regardless of the presence of the activator element.

An additional aim of the present invention is to make available a nebuliser ampoule provided with an activator element which does not interfere with the fluid dynamics of the spray in correspondence with the so-called aerosol generation plane, this term defining the space of the ampoule just outside the cone and around it.

Yet another aim of the present invention is to obtain a nebuliser ampoule

provided with means for selecting the dimensions of the particles present in the spray, to improve the therapeutic effect of the medical product dispensed by the ampoule.

Said aims are fully achieved by the nebuliser ampoule, in particular for aerosol therapy, of the present invention, which is characterised by the content of the claims set out below, ~~and in particular in that the element for~~ activating the nebulisation is physically separate from the element for distributing the medical product. The term "physically separate" means that the activator element is not made in a single piece with the distributor element and hence is distinct therefrom. However, it would be possible to interconnect the activator element and the distributor element, for instance by means of a snap-on coupling.

In particular, the distributor element comprises at least a nozzle for injecting a primary flow of air inside the ampoule to generate the nebulisation. The distributor element is provided with at least a preferably conical coating body, inserted on the nozzle and provided with at least a channel to convey the ~~medical product from a tank of the ampoule to a nebulisation area.~~

BEST MODE FOR CARRYING OUT THE INVENTION.

These aims and other aims will become more readily apparent from the description that follows of a preferred embodiment illustrated, purely by way of non limiting example, in the accompanying drawing tables, in which:

- Figure 1 shows a partially section front view of an apparatus for aerosol therapy provided with a nebuliser ampoule according to the invention;
- Figure 2 shows a top view of the apparatus of Figure 1;
- Figure 3 shows a lateral view of the ampoule of the apparatus shown in

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CLAIMS

(97)

1. Nebuliser ampoule (2), in particular for aerosol therapy, of the type
~~comprises:~~ ^{comprising:}

~~at least a mouthpiece (3) for dispensing a nebulised medical product;~~

~~at least an element (4) for distributing the medical product;~~

5 ~~at least an element (5) for activating the nebulisation,~~

~~characterised in that the activator element (5) is physically separate from the
 element (4) for distributing the medical product,~~

2. ~~Nebuliser ampoule as claimed in claim 1, characterised in that the
^{comprising:}
 distributor element (4) comprises:~~

10 ~~at least a nozzle (6) for injecting a flow of air, called primary flow, inside the
 ampoule (2), said flow being necessary for generating the nebulisation;~~

~~at least a coating body (7) inserted on the nozzle (6) and provided with at
 least a channel for conveying the medical product from a tank (8) of the
 ampoule (2) to a nebulisation area;~~

15 ~~< > characterised in that <<>>~~ ¹
 3. Nebuliser ampoule as claimed in claim ~~1~~ ¹, characterised in that the
^{with a flat end}
 activator element (5) has a portion (5a) having substantially circular section
 and is superposed to the nozzle (6) at a pre-set distance from an outlet (6a)
 thereof.

20 ~~4. Nebuliser ampoule as claimed in claim 1, characterised in that it
 comprises means for selecting particles of the nebulisation having
 predetermined dimensions.~~

5. Nebuliser ampoule as claimed in claim 1, characterised in that it
~~comprises~~ a supplementary, or secondary, channel (9), for introducing a flow
 of air, called secondary flow, into the ampoule (2) to increase and refine the

nebulisation of the medical product. >

4. ~~6.~~ Nebuliser ampoule as claimed in claim ~~5~~⁴, characterised in that the secondary channel (9) is coaxial to the distributor element (4).

5. ~~7.~~ Nebuliser ampoule as claimed in claim ~~5~~⁴, characterised in that the activator element (5) is made of a single piece with the secondary channel (9).

6. ~~8.~~ Nebuliser ampoule as claimed in claim ~~5~~⁴, characterised in that the secondary channel (9) is provided with lateral walls (9a) which extend below an outlet (6a) of the distributor element (4) or in any case below a plane of generation of the nebulisation.

10. ~~9.~~ Nebuliser ampoule as claimed in claim ~~8~~, characterised in that ~~the~~ coating body (7) has portions (7a) defining extensions of the lateral walls (9a) of the secondary ^{channel} conduit (9). >>

15. ~~10.~~ Nebuliser ampoule as claimed in claim ~~8~~, characterised in that said lateral walls (9a) define means for selecting particles of the nebulisation having predetermined dimensions.

7. ~~11.~~ Nebuliser apparatus, in particular for aerosol therapy, characterised in that it comprises a nebuliser ampoule (2) as claimed in the previous claims.

2. Nebuliser ampoule as claimed in claim 1, wherein the portions (7a) consist of a ring connected to the coating body (7) by means of supporting elements (7b) and the ring is positioned in correspondance with lower ends of the lateral walls (9a), the lateral walls (9a) together with the ring ~~constituting~~ means for selecting particles of the nebulisation having predetermined dimensions.